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CARDIAC RHYTHM MANAGEMENT SYSTEM ADJUSTING RATE RESPONSE FACTOR FOR TREATING HYPOTENSION

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CARDIAC RHYTHM MANAGEMENT SYSTEM ADJUSTING RATE RESPONSE FACTOR FOR TREATING HYPOTENSION

Cross Reference To Related Application

This patent application is a continuation-in-part of Scheiner et al. U.S. Patent Application Serial Number 09/832,365, filed on April 10, 2001, entitled "CARDIAC RHYTHM MANAGEMENT SYSTEM FOR HYPOTENSION," and assigned to Cardiac Pacemakers, Inc., the specification of which is incorporated herein by reference in its entirety.

Technical Field

The present system relates generally to cardiac rhythm management systems and particularly, but not by way of limitation, to such a system for treating hypotension.

Background

When functioning properly, the human heart maintains its own intrinsic rhythm, and is capable of pumping adequate blood throughout the body's circulatory system. However, some people have irregular cardiac rhythms, referred to as cardiac arrhythmias. Such arrhythmias result in diminished blood circulation. One mode of treating cardiac arrhythmias uses drug therapy. Drugs are often effective at restoring normal heart rhythms. However, drug therapy is not always effective for treating arrhythmias of certain patients. For such patients, an alternative mode of treatment is needed. One such alternative mode of treatment includes the use of a cardiac rhythm management system. Such systems are often implanted in the patient and deliver therapy to the heart.

Cardiac rhythm management systems include, among other things, pacemakers, also referred to as pacers. Pacers deliver timed sequences of low energy electrical stimuli, called pace pulses, to the heart, such as via an intravascular leadwire or catheter (referred to as a "lead") having one or more electrodes disposed

in or about the heart. Heart contractions are initiated in response to such pace pulses (this is referred to as "capturing" the heart). By properly timing the delivery of pace pulses, the heart can be induced to contract in proper rhythm, greatly improving its efficiency as a pump. Pacers are often used to treat patients with bradyarrhythmias, that is, hearts that beat too slowly, or irregularly. Such pacers coordinate atrial and ventricular contractions to improve pumping efficiency. Cardiac rhythm management systems also include coordination devices for coordinating the contractions of both the right and left sides of the heart for improved pumping efficiency.

Cardiac rhythm management systems also include defibrillators that are capable of delivering higher energy electrical stimuli to the heart. Such defibrillators also include cardioverters, which synchronize the delivery of such stimuli to portions of sensed intrinsic heart activity signals. Defibrillators are often used to treat patients with tachyarrhythmias, that is, hearts that beat too quickly. Such too-fast heart rhythms also cause diminished blood circulation because the heart isn't allowed sufficient time to fill with blood before contracting to expel the blood. Such pumping by the heart is inefficient. A defibrillator is capable of delivering an high energy electrical stimulus that is sometimes referred to as a defibrillation countershock, also referred to simply as a "shock." The countershock interrupts the tachyarrhythmia, allowing the heart to reestablish a normal rhythm for the efficient pumping of blood. In addition to pacers, cardiac rhythm management systems also include, among other things, pacer/defibrillators that combine the functions of pacers and defibrillators, drug delivery devices, and any other implantable or external systems or devices for diagnosing or treating cardiac arrhythmias.

One problem faced by some patients is hypotension, that is, low blood pressure. Hypotension can result in dizziness, sometimes referred to as presyncope. Hypotension can even lead to unconsciousness, sometimes referred to as syncope. One cause of hypotension is an excess shifting of blood in the circulatory system

toward the extremities (arms and legs) and away from vital organs in the patient's head and thorax. This can occur, for example, when the patient changes posture from lying horizontal or sitting with legs elevated to a position in which the patient is sitting or standing erect. Hypotension resulting from such changes in posture is referred to herein as orthostatic hypotension. However, hypotension may also have causes other than changes in posture. For example, maintaining the same posture for an extended period of time (e.g., sitting erect during an intercontinental airplane flight) may also cause hypotension. Moreover, certain cardiovascular disorders may result in hypotension independent of postural changes, or may exacerbate orthostatic hypotension.

For example, disautonomic syncope is a problem with the autonomic nervous system. In normal patients, the autonomic nervous system constricts the blood vessels in the extremities in response to a change to a more upright posture. This venoconstriction of the blood vessels in the extremities reduces the amount of blood that would otherwise shift to the extremities when the patient changes to a more upright posture. In some patients, however, this response by the autonomic nervous system is absent, or is even reversed by a venodilation of blood vessels in the extremities. Such patients are likely to experience hypotension. Moreover, this deficient response by the autonomic nervous system may occur even without changes in posture, leading to hypotension that is not necessarily orthostatic in nature.

Another example of a cardiovascular cause of hypotension is vasovagal syncope. In normal patients, a change to a more upright posture results in an increased heart rate. For example, for a patient that is at rest, the heart rate may temporarily increase from 60 beats per minute (bpm) to 80 bpm when the patient stands up after laying horizontally. In some patients, however, this autonomic response is absent–resulting in a drop in heart rate. This may also lead to hypotension as blood shifts away from the head and thorax into the extremities. Regardless of the cause of hypotension, the resulting symptoms of dizziness or loss

of consciousness may be extremely dangerous. This is particularly so for elderly patients who are at increased risk of injury from a fall resulting from the dizziness or loss of consciousness. Hypotension is also an obvious danger for persons operating motor vehicles or other machinery. For these and other reasons, there is a need to treat hypotension to avoid these symptoms and associated risks.

Summary

A cardiac rhythm management system detects hypotension. In response to an episode of detected hypotension, it increases a rate response factor mapping a sensor-indicated metabolic need to an indicated pacing rate.

In one example, the system includes a hypotension condition detection circuit to detect a hypotension condition in a subject and to provide a hypotension detection indicator. A first sensor provides a first sensor signal correlative to the subject's metabolic need for a cardiac output. A pacing therapy output circuit provides therapy to the subject at an indicated rate. A controller is coupled to provide the indicated rate to the pacing therapy output circuit. The controller is also coupled to the hypotension condition detection circuit to receive the hypotension detection indicator. The controller is also coupled to the first sensor to receive the first sensor signal. The controller determines the indicated rate based at least in part on the first sensor signal. The controller includes a rate response factor to relate a component of the first sensor signal to the indicated rate. The rate response factor is adjusted by the controller in response to the hypotension condition indicator.

The system also includes a method. The method includes detecting, in a subject, a condition correlative to hypotension. In response to the detected condition, a rate response factor is adjusted. The rate response factor relates: (a) a pacing rate at which stimulations are delivered to the subject's heart; to (b) a sensor signal that is correlative to the subject's metabolic need for cardiac output.

Other aspects of the invention will be apparent on reading the following detailed description of the invention and viewing the drawings that form a part

thereof.

Brief Description of the Drawings

In the drawings, which are not necessarily drawn to scale, like numerals describe substantially similar components throughout the several views. Like numerals having different letter suffixes represent different instances of substantially similar components.

Figure **1** is a schematic/block diagram example of portions of a cardiac rhythm management system and portions of an environment in which it is used.

Figure **2** is a block diagram example of a hypotension detection circuit using an activity sensing circuit.

Figure **3** is a graph example of one technique for determining the indicated pacing rate from the sensor-indicated metabolic need.

Detailed Description

In the following detailed description, reference is made to the accompanying drawings which form a part hereof, and in which is shown by way of illustration specific embodiments in which the invention may be practiced. These embodiments are described in sufficient detail to enable those skilled in the art to practice the invention, and it is to be understood that the embodiments may be combined, or that other embodiments may be utilized and that structural, logical and electrical changes may be made without departing from the spirit and scope of the present invention. The following detailed description is, therefore, not to be taken in a limiting sense, and the scope of the present invention is defined by the appended claims and their equivalents.

Figure **1** is a schematic/block diagram example of portions of a cardiac rhythm management system **100** and portions of an environment in which it is used. In this example, system **100** includes, among other things, a cardiac rhythm management device **102** and leadwire ("lead") **104**, which is coupled to device **102**

for communicating one or more signals between device **102** and a portion of a living organism or other subject, such as heart **106**. Examples of device **102** include, among other things, bradycardia and antitachycardia pacemakers, cardioverters, defibrillators, combination pacemaker/defibrillators, drug delivery devices, and any other implantable or external cardiac rhythm management apparatus capable of providing therapy to heart **106**. System **100** may also include additional components such as, for example, an external or other remote interface **108** capable of communicating with device **102**.

In this example, device **102** includes, among other things, a microprocessor or other controller **110** coupled to a hypotension detection circuit **112**, a pacing therapy output circuit **114**, a metabolic need sensor **116**, and a communication circuit **118**. Communication circuit **118** is adapted for wireless communication with remote interface **108**. Pacing therapy output circuit **114** is coupled to one or more electrodes associated with any chamber(s) of heart **106**, such as electrodes **120** and **122** of lead **104**, for delivering electrical pacing stimulations for evoking responsive heart contractions. Metabolic need sensor **116** senses the subject's need for a particular degree of cardiac output of blood being pumped through the subject's circulatory system. To accommodate the sensed metabolic need, controller **110** provides pacing therapy output circuit **114** with a variable indicated pacing rate for evoking the heart contractions. A higher sensed metabolic need for cardiac output results in a higher indicated pacing rate for evoking heart contractions.

In this example, hypotension detection circuit **112** detects a hypotension condition in the subject. In response to the detected hypotension, controller **110** adjusts the indicated pacing rate. More particularly, in the presence of hypotension, controller **110** increases a rate response factor ("RRF") so that a particular degree of metabolic need results in an at least temporarily higher indicated pacing rate than if hypotension were not detected. In a further example, controller **110** communicates an indication of the hypotension condition through communication circuit **118** to remote interface **108** for display or other user output.

One example of metabolic need sensor **116** is an activity sensor that senses the subject's activity. A greater activity level corresponds to a greater metabolic need for cardiac output of blood pumped through the circulatory system. One particular example of an activity sensor is an accelerometer for sensing the subject's movement, which is deemed correlative to the subject's activity and, therefore, to the subject's metabolic need. One suitable example of an accelerometer-based activity sensor of metabolic need is discussed in Meyerson et al. U.S. Patent No. 5,179.947 entitled "ACCELERATION-SENSITIVE CARDIAC PACEMAKER AND METHOD OF OPERATION," which is assigned to Cardiac Pacemakers, Inc., and the disclosure of which is incorporated herein by reference in its entirety. Another example of an activity sensor is a breathing (or "respiration" or "ventilation") sensor that senses the subject's breathing rate. A higher breathing rate is deemed to correspond to a higher activity level, which, in turn, corresponds to a greater metabolic need.

One particular example of a respiration sensor is a transthoracic impedance sensor that detects an impedance across a portion of a subject's thorax ("thoracic impedance" or "transthoracic impedance.") In this document, the term "thorax" refers to the subject's body other than the subject's head, arms, and legs. As the subject breathes, inhaling and exhaling (also referred to as inspiration and expiration) the thoracic impedance varies as modulated by the breathing. From these thoracic impedance variations, the breathing rate can be determined.

In such an thoracic impedance respiration sensor example, metabolic need sensor **116** is coupled to the patient's thorax by at least two electrodes for determining the thoracic impedance by providing a test signal and measuring a response signal. In one suitable thoracic impedance respiration sensor example, system **100** includes a configuration of at least four electrodes for detecting thoracic impedance, such as discussed in Hauck et al. U.S. Patent 5,284,136 entitled "DUAL INDIFFERENT ELECTRODE PACEMAKER," assigned to Cardiac Pacemakers, Inc., the disclosure of which is incorporated herein by reference in its entirety.

However, a different number of electrodes (e.g., 2 or 3 electrodes, or more than 4 electrodes) could also be used. One suitable example of a metabolic need sensor **116** based on thoracic impedance detection of respiration uses a high frequency carrier signal to provide a test stimulus and obtain a thoracic impedance response, as discussed in Hartley et al. U.S. Patent No. 6,076,015 ("the Hartley et al. patent") entitled "RATE ADAPTIVE CARDIAC RHYTHM MANAGEMENT DEVICE USING TRANSTHORACIC IMPEDANCE," assigned to Cardiac Pacemakers, Inc., the disclosure of which is incorporated herein by reference in its entirety.

In this example, hypotension detection circuit **112** detects a hypotension condition in the subject. One example of a suitable hypotension detection circuit **112** is discussed in Scheiner et al., U.S. Patent Application Serial No. 09/832,365, filed on April 10, 2001, entitled "CARDIAC RHYTHM MANAGEMENT SYSTEM FOR HYPOTENSION," and assigned to Cardiac Pacemakers, Inc., the disclosure of which is incorporated herein by reference in its entirety. The Scheiner et al. patent application discusses sensing thoracic impedance, such as in the Hartley et al. patent, using an electrode configuration such as that discussed in the Hauck et al. patent.

The thoracic impedance signal is influenced by the patient's thoracic intravascular fluid tension, heart beat, and breathing (also referred to as "respiration" or "ventilation"). A "dc" or "baseline" or "low frequency" component of the thoracic impedance signal (e.g., less than a cutoff value that is approximately between 0.1 Hz and 0.5 Hz, inclusive, such as, for example, a cutoff value of approximately 0.1 Hz) provides information about the subject patient's thoracic fluid tension, and is therefore influenced by intravascular fluid shifts to and away from the thorax. Higher frequency components of the thoracic impedance signal are influenced by the patient's breathing (e.g., approximately between 0.05 Hz and 2.0 Hz inclusive) and heartbeat (e.g., approximately between 0.5 Hz and 10 Hz inclusive).

As discussed above, a too-low intravascular fluid tension in the thorax

("thoracic hypotension") may result from changes in posture. This is sometimes referred to as orthostatic hypotension. For example, in a person who has been in a recumbent position for some time, approximately 1/3 of the blood volume is in the thorax. When that person then sits upright, approximately 1/3 of the blood that was in the thorax migrates to the lower body. This increases thoracic impedance. Approximately 90% of this fluid shift takes place within 2 to 3 minutes after the person sits upright.

Aside from such changes in posture, however, thoracic hypotension may also manifest itself as disautonomic syncope or vasovagal syncope, or other condition in which intravascular fluid shift from the thorax may or may not correspond directly to a change in the patient's posture. However, hypotension resulting from a fluid shift away from the thorax is indicated by an increase in the baseline thoracic impedance, regardless of whether the cause of the hypotension is orthostatic. In response to the detection of hypotension, controller **110** increases the rate response factor relating the degree of metabolic need sensed by metabolic need sensor **116** to the indicated pacing rate at which pacing stimulations are provided by pacing output therapy circuit **114**.

Figure **2** is a block diagram example of another hypotension detection circuit **112** using an activity sensing circuit **200**. In one example, activity sensing circuit **200** includes an accelerometer circuit sensing the subject's motion, which is deemed correlative to the subject's activity, and providing at node **202** a resulting substantially instantaneous activity level (AL) output signal indicative of the subject's activity. In another example, activity sensing circuit **200** includes a respiration circuit (using the thoracic impedance technique discussed above or any other suitable technique for detecting a breathing rate) sensing the subject's breathing rate, which is deemed correlative to the subject's activity, and providing at node **202** a resulting substantially instantaneous AL output signal indicative of the subject's activity. An input of lowpass filter (or averager) **204** is coupled to receive the substantially instantaneous AL signal for lowpass filtering or averaging over an

extended period of time, such as approximately between 15 minutes and 24 hours. Filter **204** outputs at node **206** a resulting long-term AL signal. The substantially instantaneous AL at node **202** is compared to a threshold value A at node **208** by comparator **210**. The long-term AL at node **206** is compared to a threshold value B at node **212** by comparator **214**. If the substantially instantaneous AL exceeds threshold A and the threshold B exceeds the long-term AL, then the subject is deemed to have transitioned from a period of rest to a period of activity. This detected transition is, in turn, deemed to correspond to an onset of orthostatic hypotension as communicated by the output of hypotension detection circuit, at node **216**, to controller **110**. The signal processing illustrated in Figure **2** can be performed in either analog or digital domains.

Although hypotension detection circuit **112** and metabolic need sensor **116** are illustrated in Figure **1** as being implemented separately, in certain examples these blocks may share certain components. For example, where an accelerometer is used as metabolic need sensor **116** and hypotension detection circuit **112** also uses an accelerometer-based activity sensing circuit **200**, the same accelerometer can be used for both. Similarly, where thoracic impedance sensing of breathing is used as metabolic need sensor **116** and hypotension detection circuit **112** uses a thoracic impedance baseline for determining whether hypotension is present, the same test signal generation, receiving, and demodulation circuit could be used in both blocks, with appropriate separate processing of different frequency components of the thoracic impedance signal.

Figure **3** is a graph example of one technique executed by controller **110** for determining the indicated pacing rate **300** from the sensor-indicated metabolic need **302** received by controller **110** from metabolic need sensor **116**. In this example, line **304** indicates one mapping of metabolic need to the indicated pacing rate, which is bounded by a lower rate limit (LRL) and a maximum sensor rate (MSR). A greater metabolic need corresponds to a higher indicated pacing rate, therefore line **304** has a positive slope. The slope of line **304** is referred to as the rate response

factor (RRF). The RRF is typically programmable to a particular value within a range of values. In operation, upon receiving an indication of a detected episode of hypotension from hypotension detection circuit **112**, controller **110** increases the RRF from its programmed value, RRF_1, to a higher value, RRF_2, for a time period following the detection of hypotension, and then returns to RRF_1. In one example, this time period is approximately between 30 seconds and 10 minutes, such as about 2 minutes. During this time period, line **306** illustrates the mapping of metabolic need to indicated pacing rate. Thus, when hypotension is detected, a particular level of sensor-indicated metabolic need results in a higher value of the indicated pacing rate than when no hypotension is present. Controller **110** provides the indicated pacing rate to pacing therapy output circuit **114**, which, in turn, provides pacing stimuli to heart **106** at the indicated pacing rate.

For example, when activity is used to indicate metabolic need, when hypotension is detected the indicated pacing rate is increased. The increase in indicated pacing rate is larger at higher activity levels than at lower activity levels. By increasing the indicated pacing rate in this manner, controller **110** effects a faster return of blood from the extremities to the thorax and head, thereby reducing or avoiding the symptoms of dizziness or fainting.

In an alternative example, rather than abruptly being stepped back from RRF_2 to RRF_1 following the time period initiated by the detected hypotension, the mapping slope more slowly decays, or otherwise incrementally steps back to the programmed value. In one example, the RRF approximately exponentially decays from RRF_2 to RRF_1, such as with a time constant that is approximately between 15 seconds and 10 minutes, such as about 1 minute. In another example, the RRF incrementally steps from RRF_2 to RRF_1 through a number of intermediate values that are substantially equally spaced between RRF_2 and RRF_1.

It is to be understood that the above description is intended to be illustrative, and not restrictive. For example, the above-discussed embodiments may be used in combination with each other. Many other embodiments will be apparent to those of

skill in the art upon reviewing the above description. The scope of the invention should, therefore, be determined with reference to the appended claims, along with the full scope of equivalents to which such claims are entitled. In the appended claims, the terms "including" and "in which" are used as the plain-English equivalents of the respective terms "comprising" and "wherein."